REMARKS

I. STATUS OF THE CLAIMS

Claims 14-28 were pending at the time of the Action. Claims 14, 23, 24, and 25 have been amended. Claims 15, 16, 18, 19, 21, 22 and 26-28 have been cancelled without prejudice or disclaimer. Support for "full length" SEQ ID NO:65 in claim 14, can be found throughout the disclosure as well as in the Sequence Listing. Support for the phrase including "the presence of said nucleic acid in a sample of a subject indicates that the subject has an increased risk of idiopathic generalized epilepsy" in claim 24 can be found in the specification, for example at pages 52 and 54-59 (Examples 3, 6, and 7). Support for the phrase "a deletion mutation at positions 759 to 761 of SEQ ID NO: 65" in claim 25(a), can be found in the specification, for example from page 53, line 21 to page 54, line 4, at page 27, lines 24 to 28 and in the Sequence Listing. Support for the phrase "a G to A mutation at position 3735 of SEQ ID NO: 65" in claim 25(b), can be found in the specification, for example at page 54, lines 9 to 10, as well as in Figure 7 and in the Sequence Listing. No new matter has been entered by way of the instant amendment.

Claims 14, 17, 20, 23, 24 and 25 are now pending.

II. INFORMATION DISCLOSURE STATEMENTS

A. Information Disclosure Statement filed October 16, 2006:

Reference C77: Applicants acknowledge that reference C77 was a duplicate and had already been considered by the Examiner.

B. Information Disclosure Statement Filed January 29, 2007:

Reference C79: As requested by the Examiner, relevant pages of reference C79 are being submitted in a Supplemental Information Disclosure Statement concurrently with this

response. More particularly, pages 1-12, 38-50 and 80-83 are being submitted together with the table of contents of the Journal.

Reference C81: Reference C81 was received from Examiner Sue Liu in an Office Action dated November 11, 2006, issued in parent application No. 10/664,603. More particularly, the blast result submitted as reference C81 was provided by the Examiner with regard to comparison of portions of SCN3A sequences (SEQ ID NOs:72 and 73 of the instant Sequence listing). The Examiner used this sequence alignment to demonstrate that the sequences do not share significant sequence similarity.

III. CLAIM OBJECTIONS

Claim 15 is objected to under 37 CFR 1.75(c) as being of improper dependent form for failing to further limit the subject matter of a previous claim. In view of the cancellation of claim 15, any objection thereto is moot.

IV. REJECTIONS UNDER 35 U.S.C. §112

A. Claims 14-28 Are Enabled by the Specification

Claims 14-28 are rejected under 35 U.S.C. § 112, first paragraph as not complying with the enablement requirement. Specifically, the claims are rejected based on alleged insufficient enablement for all complements, fragments, or variants encompassed by claims 14-16.

Applicants disagree as the claims are enabled by the specification. However, in an effort to further the prosecution of this case and secure prompt allowance, claim 14 has been revised and claims 15 and 16 have been cancelled. Claim 14 is now directed to a nucleic acid molecule selected from the group consisting of (a) the nucleic acid of SEQ ID NO:65; which encodes an alpha subunit of a sodium channel; (b) a full length complement of (a); and (c) a nucleic acid

sequence having at least 95% identity to the full length nucleic acid sequence in (a) or (b). In view of the above, the enablement rejection is moot and should be withdrawn.

For the record, it is submitted that Applicants still believe that the rejected claims are enabled and satisfy the written description requirement as set forth in the response dated January 22, 2007. Applicants reserve the right to pursue fragments, functional derivatives and allelic variants in further applications.

B. Claims 14-28 Satisfy the Written Description Requirement

Claims 14-27 have been rejected under 35 U.S.C. §112, first paragraph as failing to comply with the written description requirement. Specifically, the Action alleges that the description of the application would not reasonably convey to one of skill in the art that the Applicants had possession of nucleic acid sequences for any fragment, functional derivative, or allelic variant of the claimed sequences.

Applicants disagree as the claims satisfy the written description requirement. However, in an effort to further the prosecution of this case and secure prompt allowance, claim 14 is now directed to nucleic acids having at least 95% identity to the full length of SEQ ID NO:65 and claims 15, 16, 18, 19, 21, 22, 26 and 27 have been cancelled. In view of the above, the written description rejection is moot and should be withdrawn.

For the record, Applicants note that the rejected claims satisfy the written description requirement as set forth in the response dated January 22, 2007. Applicants reserve the right to pursue fragments, functional derivatives and allelic variants in further applications.

C. Claims 25–27 Satisfy the Written Description Requirement

Claims 25-27 have been rejected under 35 U.S.C. § 112, first paragraph as failing to comply with the written description requirement. Specifically, the Action first alleges that the description of the application would not reasonably convey to one of skill in the art that the

Applicants had possession of the two specific mutations and combination thereof recited in claim 25 parts (a)-(c) which are considered as new matter.

Applicants respectfully submit that one must not place undue emphasis on the presence or absence of literal support in the specification for the claim language. The test is whether the disclosure of the application as originally filed "reasonably conveys to the artisan that the inventor had possession at the time of the later claimed subject matter" *In re Kaslow*, 707, F.2d 1366 (Fed. Cir. 1983). Applicants submit that support for the position of the two mutations listed in claim 25(a) and 25(b) may be inferred from the disclosure as originally filed. More particularly, the mutation in part (a) of claim 25 (a deletion mutation at positions 759 to 761 of SEQ ID NO:65) corresponds to a deletion at amino acid residue 43 of SCN3A (or a mutation in the following nucleotide sequence: CAA GAT --- GAT GAT GAG) as described at page 53, lines 23 to 27 as well as in Figure 7.

Likewise, the G to A mutation at position 3735 of SEQ ID NO:65, described in part (b) of claim 25, is supported by the disclosure at page 54, lines 9-15 as well as in Figure 7 (mutation Val1035Ile of SEQ ID NO:67 or mutation in the following sequence AAA TAC RTA ATC GAT).

Thus, having disclosed not only the nucleic acid (cDNA) and protein sequence of SCN3A (corresponding to SEQ ID NOS:65 and 67, respectively - See page 27, lines 24 to 27 and the Sequence Listing) but also the portions of the nucleotide sequence surrounding the identified mutations (page 53, line 26 and page 54, line 10), one skilled in the art can easily identify the corresponding nucleotide positions in SEQ ID NO:65 as being 759 to 761 (for the deletion mutation) and position 3735 (for the Val1035Ile mutation). Accordingly, the specification as

originally filed, supports a deletion mutation at positions 759-761 and a G to A mutation at position 3735 of SEQ ID NO:65.

In order to expedite the prosecution of the instant application, Applicants have deleted part (c) from claim 25 without prejudice or disclaimer. For the record however, Applicants submit that support for claim 25, part (c), relating to combinations of the mutations listed in parts (a) to (b), can be found at page 21, line 15 and at page 22, lines 2-5. In addition, given that the individually described mutations were discovered in the SCN1A gene of patients suffering from epilepsy (and are thus readily found in nature), one skilled in the art can easily expect to find a combination of the above-described mutations in nature, based solely on the possibility that two parents, each carrying one of the above-described mutations, could give birth to a child carrying two mutations. Thus, the combination of mutations described in claim 25, part (c) is not any combination of mutations but combinations that are expected to be found in nature based on Applicants' disclosure.

In view of the above, of the amendments to claim 25 and of the cancellation of claims 26 to 27, it is respectfully requested that the Examiner withdraw his rejection of claims 25-27 under 35 U.S.C. §112, first paragraph.

D. Claims 15 and 23-25 Are Definite

Claims 15 and 23-25 have been rejected under 35 U.S.C. §112, second paragraph as failing to particularly point out and claim the subject matter which the Applicants regards as their invention.

Applicants disagree, as a person of ordinary skill in the art would understand the full scope of the claims when read alone, or in light of the specification. However, in an effort to further the prosecution of this case and secure prompt allowance, claim 24 has been amended as suggested by the Examiner, to recite "... indicates that the subject has an increased risk of

idiopathic generalized epilepsy". In view of the cancellation of claims 15 and 26, any objections under 35 U.S.C. §112, second paragraph thereto are moot.

V. REJECTIONS UNDER 35 USC § 102

A. Claims 14-24 Are Not Anticipated by the Clare Reference

Claims 14-24 have been rejected as being allegedly anticipated by Clare *et al.* (Conference on Molecular and Functional Diversity of Ion Channels and Receptors, New York, NY May 14-17, 1998, published as Annals of the New York Academy of Sciences 1999, 868:80-83). Applicants respectfully traverse the rejection as follows.

To anticipate a claim, each and every element of the claim must be found either expressly or inherently described in a single prior art reference. *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987).

Applicants disagree with the Examiner as the cited reference fails to disclose every element of the claims. However, in an effort to further the prosecution of this case and secure prompt allowance, claim 14 is currently directed to SEQ ID NO:65, a full length complement thereof, or a nucleic acid sequence with at least 95% identity to the full length of either of the above, none of which are taught by Clare.

The Examiner cites *In re Best* to put the burden on the Applicants to distinguish what is claimed from the product disclosed. Unfortunately, Applicants are unable to demonstrate whether the nucleic acid on the Northern blot on Figure 2 is the same or is different from the claimed nucleic acids. In order to compare the products, the Applicants would have to obtain the Northern blot from Clare, excise the band and sequence it. Alternatively, they would have to obtain the cells expressing the cloned channel in order to sequence the channel. This however, is not possible. Therefore it follows that one skilled in the art, looking at the claimed nucleic acids

and at the publication from Clare, could not determine with any certainty if the nucleic acids are the same or if they are different as Clare does not disclose the specific sequence of the cloned nucleic acid. In addition, looking at the Northern blot in Figure 2 of Clare, one skilled in the art would appreciate that there is a possibility that the claimed nucleic acids are different from the one on the Northern blot since the claimed nucleic acids are 9.112 kb and the nucleic acid on the Northern blot is 9.5 kb.

Thus, in addition to the fact that Clare is an unenabling disclosure with regard to specific nucleic acid sequences, it is apparent from the above that there remains a clear possibility that the claimed nucleic acids sequences are different from the nucleic acids disclosed by Clare.

Thus, in view of: 1) the above-described evidence (as well as other reasons of record submitted in the response of August 21, 2006) showing that inherency is clearly not "certain" based on Clare *et al.*; 2) the amendment to claim 14; and 3) the cancellation of claims 15, 16, 18, 19, 21, 22 and 26-28, Applicants respectfully request that the Examiner withdraw the rejection of claims 14-24 under 35 U.S.C. §102 (b).

B. Claims 14-19 and 23-24 Are Not Anticipated by the Lu Reference

Claims 14-19 and 23-24 have been rejected as being allegedly anticipated by Lu et al. (1998. Journal of Molecular Neuroscience 10(1):67-70).

Applicants disagree as the cited reference fails to disclose every element of the claims. However, in an effort to further the prosecution of this case and secure prompt allowance, claim 14 is currently directed to SEQ ID NO:65, a full length complement thereof, or a nucleic acid sequence with at least 95% identity to the full length of either of the above, none of which are taught by Lu.

Applicants request that the anticipation rejections be withdrawn.

VI. CONCLUSION

Applicants believe that the present document is a full and complete response to the Action dated April 27, 2007. The present case is in condition for allowance, and such favorable action is respectfully requested.

The Examiner is invited to contact the undersigned Attorney at (512) 536-3167 with any questions, comments or suggestions relating to the referenced patent application.

Respectfully submitted,

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